PTO-1390 (Rev. 12-2004)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTTORNEY'S DOCKET NUMBER 3084 LISOP

DESIGNATED/ELECTED	U.S. APPLICATIONING. (TAGOWIT, See 177 OFR 1.5)								
CONCERNING A SUBMISSION	10/720/4/								
INTERNATIONAL APPLICATION NO. PCT/JP03/08790	INTERNATIONAL FILING DATE July 10, 2003	PRIORITY DATE CLAIMED July 11, 2002							
TITLE OF INVENTION PRODUCTION METHOD OF COATED PREPARATIONS									
APPLICANT(S) FOR DO/EO/US									
Masahiko KOIKE; Hiroyoshi KOYAMA; Naoru HAMAGUCHI									
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:									
1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.									
2. This is a SECOND or SUBSEQUENT	submission of items concerning a submissio	n under 35 U.S.C. 371.							
 This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 									
4. The US has been elected (Article 31).									
5. A copy of the International Application as filed (35 U.S.C. 371(c)(2))									
a. is attached hereto (require	a. is attached hereto (required only if not communicated by the International Bureau).								
b. An has been communicated b	y the International Bureau.								
	ication was filed in the United States Receiv	ing Office (RO/US).							
6. An English language translation of th	An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).								
a. is attached hereto.									
	itted under 35 U.S.C. 154(d)(4).								
	ernational Application under PCT Article 19								
	ired only if not communicated by the Interna	tional Bureau).							
	by the International Bureau.								
	c. have not been made; however, the time limit for making such amendments has NOT expired.								
a. Santave not seen made and	d. 🗹 have not been made and will not be made.								
	An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).								
	An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).								
10. An English language translation of the Article 36 (35 U.S.C. 371(c)(5)).	An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).								
Items 11 to 20 below concern document(s) or information included:								
11. An Information Disclosure Statemen	t under 37 CFR 1.97 and 1.98. Cited F	References							
l = '	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.								
13. A preliminary amendment.	A preliminary amendment.								
14. An Application Data Sheet under 37	An Application Data Sheet under 37 CFR 1.76.								
15. A substitute specification.	A substitute specification.								
16. A power of attorney and/or change of	A power of attorney and/or change of address letter.								
17. A computer-readable form of the sec	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.								
18. A second copy of the published Inter	A second copy of the published International Application under 35 U.S.C. 154(d)(4).								
l <u> </u>	A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). Return Postcard; Certificate of Express Mailing; PCT Request; Cover Page International Application; Forms								
	Other items or information: PCT/IB/301,304,306;308;332; ISR								

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. APPLICATION NO. (if known, see 37 CER 1.5) INTERNATIONAL APPLICATION NO.				ATTORNEY'S DOCKET NUMBER			
10/520/4/ PCT/JP03/08790					3084 US0P		
l	ng fees are submitted:				\$		
	itional fee		+				
b) Examination fee\$200.00					\$		
C) Search fee\$500.00					\$	<u> </u>	
TOTAL OF ABOVE CALCULATIONS = \$1000.00					\$ 1,000.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence							
listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.							
Total Sheets	Extra sheets	Extra sheets Number of each additional 50 or fraction thereof (round up to a whole number)					
26 - 100 =	/50 =	1		× \$250.00	\$		
		oath or dec	claration later than 30 months fro	om the earliest	\$		
	late (37 CFR 1.492(e)).						
CLAIMS	NUMBER F		NUMBER EXTRA	RATE	\$	T .	
Total claims	<u>'</u>	- 20 =	0	x \$50.00	\$ O		
Independent clai		- 3 =	0	x \$200.00	\$ 0		
MULTIPLE DEPI	ENDENT CLAIM(S) (if a	pplicable)		+ \$360.00	\$		
TOTAL OF ABOVE CALCULATIONS = Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced				· ·			
by ½.	iaims smail entity status	s. See 37 C	FR 1.27. The fees indicated ab	ove are reduced	\$		
SUBTOTAL =					= \$ 1,000.00		
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					t \$		
TOTAL NATIONAL FEE =				= \$ 1,000.00	\$ 1,000.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					\$		
TOTAL FEES ENCLOSED =					= \$ 1,000.00		
				Amount to be refunded:	\$		
					Amount to be charged:	\$	
a. A check in the amount of \$ to cover the above fees is enclosed.							
b. Please charge my Deposit Account No. 500799 in the amount of \$ 1,000.00 to cover the above fees. A duplicate copy of this sheet is enclosed.							
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 500799—A duplicate copy of this sheet is enclosed.							
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.							
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.							
SEND ALL COR	RESPONDENCE TO:					>	
Mark Chao, Ph.D., JD						•	
Takeda Pharmaceuticals North America, Inc SIGNATURE			RE	····			
				Chao, Ph.D., JD			
Lincolnshire, IL 60069 USA NAME							
(847)383-337	2 fax (847)383-3409				37,293		
					TION NUMBER omer No.,23,115		

FORM PTO-1390 (REV. 12-2004)

Page 2 of 2

DT15 Rec'd PCT/PTO 10 JAN 2005

IN THE UNIT STATES PATENT AND TRADEMARK OFFICE

Application No.:

Based on PCT/JP03/08790

Filed:

Intl. Filing 10 JULY 2003

1st Inventor:

Masahiko KOIKE

For:

Production Method of Coated Preparations

Atty. Dkt. No.

3084 US0P

Art Unit:

tha

Examiner:

tba

Allowed:

Batch:

Paper No.:

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EV 524906932 US

DATE IN:

January 10, 2005

Itemized Papers/Items:

- 1. This Certificate of Express Mailing and ReturnPostcard (2 pages)
- 2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
- 3. Specification total pages (26 including Claims 1-12 (pages 24-25), and Abstract (1 page)
- 4. PCT Request (5 pages)
- 5. Declaration and Power of Attorney (4 pages)
- 6. Copies of Forms PCT/IB/301, 304, 306, 308, 332 (6 pages)
- 7. Copy of Cover Page International Application (WO 2004/006921) (1 page)
- 8. Copy of International Search Report (2 pages)
- 9. Preliminary Amendment (2 pages)
- 10. Information Disclosure Statement (1 page), Form PTO/SB/08A (2 pages), cited references (9)
- 11. Credit Card Payment Form (1 page)
- 12. Executed Assignment (2 pages) and Recordation Cover Sheet (1 page X 2)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP PCT P.O. BOX 1450

Commissioner for Patents

Alexandria, VA 22313-1450

on this date, 1/10/05

Dated: 1/10/05

Goil I Winglaur

Takeda Pharmaceuticals North America, Inc. Intellectual Property Department 475 Half Day Road Lincolnshire, IL 60069 USA